

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: THE WAVE 3 CASES LISTED IN DEFENDANTS' EXHIBIT A	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**PLAINTIFFS' RESPONSE TO ETHICON'S MOTION TO EXCLUDE OR LIMIT THE
OPINIONS AND TESTIMONY OF DR. RUSSELL DUNN**

Plaintiffs submit the following Memorandum of Law in opposition to the “Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D.” filed by Defendants Ethicon, Inc. and Johnson & Johnson (collectively “Ethicon”).¹ Ethicon’s Wave 3 Motion is almost entirely duplicative of its Wave 1 and 2 *Daubert* Motions to limit or exclude Dr. Dunn’s testimony and it should be denied for the same reasons detailed in Plaintiffs’ Wave 2 *Daubert* Response [Doc. 2647], incorporated by reference hereto.²

PLAINTIFFS' ADDITIONAL RESPONSE TO ETHICON'S MOTION

1. Nothing new is being argued by Ethicon in this Wave 3 *Daubert* Motion.

Dr. Dunn adopted his Wave 1 report for the Wave 3 cases at issue. On September 2, 2016, the Court entered a Memorandum Opinion and Order [Doc. 2725] regarding Ethicon’s Wave 1 *Daubert* Motion to limit Dr. Dunn’s testimony for Wave 1. In that Order, the Court

¹ For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. Plaintiffs incorporate by reference the state of review for *Daubert* motion as articulated by the Court in this litigation. See Mem. Op. and Order (*Daubert* Motion re: Russell Dunn, Ph.D.), No. 2:12-md-02327, at 5-6 (S.D. W. Va. Sept. 2, 2016) [Doc. 2725].

² Ex. A, Plaintiffs’ Wave 2 *Daubert* Response for Dunn.

considered the issue of Ethicon’s compliance with “design control and risk management standards,” but reserved ruling on such matters because “the nuances of products liability law vary by state.” Doc. 2725 at 8. The Court found that “[e]ach standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law.” *Id.*

Ethicon’s Wave 3 Motion addressing Dr. Dunn’s opinions in these cases puts forth the same arguments that were made by it in both Waves 1 and 2. Def. Brief at 2-19. No new evidence or expert testimony has been provided by Dr. Dunn for Wave 3 and, moreover, as the Court has recognized, part of the *Daubert* analysis is to determine whether his opinions fit each case—which requires an analysis of what is relevant under state law. *See* Doc. 2725 at 8. All of Ethicon’s renewed attacks on Dr. Dunn’s opinions, therefore, should be denied.

2. Ethicon’s Wave 3 Motion is based on International Standards trumping all else.

In addition, although Dr. Dunn is an unquestioned expert in product design and risk analyses, like the Failure Modes Effects Analysis (“FMEA”), which is mandated for use in all of Ethicon’s products—Ethicon is still arguing that Dr. Dunn is unqualified to offer his opinions because he does not have requisite experience applying International Standards (“ISO”) to medical device design. Def. Brief at 2-19. As the Court found in Wave 1, however, this argument is unavailing:

“Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product’s risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.” [Doc. 2725 at 7-8]

Indeed, not only is Ethicon’s Wave 3 *Daubert* Motion based on an argument that is a complete misstatement of the state of device design and risk assessment—it is also contrary to what the

Court found when it examined these issues in Wave 1 and decided to reserve ruling until a state-specific inquiry could be made.

3. Plaintiffs never conceded that Dr. Dunn doesn't have the expertise to determine if Prolene is subject to degradation or oxidation.

In addition, Ethicon takes liberties with Plaintiffs' concession in their Wave 1 Response that Dr. Dunn "has not, and will not, [provide] an opinion as to how Ethicon's Prolene undergoes oxidation inside the body" and argues that he is unqualified to render an opinion on if Prolene undergoes degradation.³ Def's brief at 2. Dr. Dunn is a polymer chemist, chemical engineer, and expert in product design and the use of risk analyses. He has all of the requisite knowledge, experience and expertise to review evidence of Prolene's degradation (in the form of internal documents showing degradation via FTIRs, SEMs and other analyses performed on explanted samples) to hold an opinion that degradation is, in fact, occurring.

As Plaintiffs' previously stated, Dr. Dunn will not be testifying as to the mechanism by which *in vivo* degradation occurs, but his report describes all of the internal degradation studies produced by Ethicon in this litigation and he holds the opinion that the SEMs, FTIRs and other analyses performed show that Prolene degradation appears on explanted samples.⁴ Additionally, this Court has held that Ethicon's own expert, Shelby Thames, Ph.D, cannot testify that Ethicon's internal studies showed no losses in molecular weight—which is contrary to Ethicon's argument that Prolene is immune to degradation. Thames Memorandum and Order [Doc. 2723 at 6]. "Specifically, although the study reported no significant difference in molecular weights, Dr. Thames reports the study as finding no molecular weight change... Insofar as Dr. Thames's testimony mischaracterizes the dog study's results on molecular weight change, it is

³ Ex. B., Plaintiffs' Wave 1 Dunn Resp. at 9 [doc. 2173]

⁴ Ex. C, Dunn Report at 15-17.

EXCLUDED.” *Id.*, citations omitted. As such, Plaintiffs respectfully request that the Court allow Dr. Dunn’s opinions and testimony contained in Dr. Dunn’s report to be heard at trial, for these reasons and those expressed in Plaintiffs’ Wave 2 *Daubert* Response.

Dated: October 11, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace_____